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PATENT

#7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jürgen MARKL, et al.

) Group Art Unit:

) Not Yet Assigned

)

Serial No: 09/936,852

) Examiner: Not Yet Assigned

)

Filed: September 27, 2001

) Attorney Docket No: GKS-101.0

)

(83687)

For: NUCLEIC ACID MOLECULE COMPRISING
A NUCLEIC ACID SEQUENCE CODING FOR
A HEMOCYANIN

) Confirmation No. 1442

)

INFORMATION DISCLOSURE STATEMENT

Commissioner For Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.97, a list of documents that may be material to the examination of this application is provided on the attached Form PTO-SB08. Listed Documents A1-A3, and A6-24 are U.S. or foreign patents or pertinent articles that may be relevant to the examination of the present application. The publications listed thereupon generally relate to subject matter of the invention, but do not fairly teach or suggest the claimed Nucleic Acid Molecule Comprising a Nucleic Acid Sequence Coding for a Hemocyanin. Copies of the listed publications are enclosed for consideration by the Examiner.

Listed Documents A1-A2 and A7-A22 were listed on the International Search Report by the International Searching Authority in the parent case, International Patent Application No. PCT/EP 00/02410. The relevance of that art, in the opinion of the international

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patent examiner, is stated on the International Search Report, which has already been provided. It is respectfully noted that several of the documents are marked "P" thereupon, because the documents were published after the foreign priority filing date, but before the international filing date.

Document A1, U.S. Patent No. 5,888,775, discloses peptide synthesis and purification by fusion to *penI* protein or precipitation effective portion thereof.

Document A2, U.S. Patent No. 5,831,033 discloses human thymosin β 15 gene, protein and uses thereof.

Document A3, U.S. Patent No. 5,021,560 is the English version of Document A9, EP 0 252 829, cited by the International Search Authority, thus serving as the English translation thereof, both of which disclose immunogenic glycoprotein extract fractions from hemocyanin of a mollusc, which is active against bilharzioses, and its preparation, and immunizing compositions containing it.

There are no documents labelled A4 and A5.

Document A6 listed on the attached Form PTO-1449 is the published PCT application corresponding to the present U.S. patent application, for which the benefit of priority is claimed and disclosures thereof incorporated by reference. A copy of the first page of document A6 is provided herewith. This page shows the international filing date of March 17, 2000, and the two priority German filing dates of March 17, 1999 and August 20, 1999.

Document A7, WO 94/11019, discloses zona pellucida proteins or immunocontraceptively active fragments thereof for immunocontraception.

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Document A8, EP 0 244 295 A1, discloses an immunogen isolated from molluscs, and their process of preparation, reactive agents for diagnostics of human bilharzioses, caccins against schistosomaises, and immunizing compositions comprising these immunogens. This document was cited in the International Search Report, but there was no corresponding English language translation that we located. A more complete translation of this document will be provided upon request of the Examiner. Glycoprotein extract from molluscs, notably *Megathura crenulata*, including hemocyanin, that present the same antigenic properties as the 38 kD antigen isolated from the surface of schistosomule of *S. mansoni*, are oligosaccharide epitopes. Protective serum guard against infections from *S. manson*,

Document A11 discloses periodate-sensitive immunological cross-reactivity between keyhole limpet haemocyanin (KLH) and serodiagnostic schistosoma mansoni egg antigens.

Document A12 discloses sequence of the octopus dofleini hemocyanin subunit: structural and evolutionary implications.

Document A13 discloses primary structure and unusual carbohydrate moiety of functional unit 2-c of keyhole limpet hemocyanin (KLH). The publication date of Document A13, November 16, 1999, is after both of the filing dates of the German patent applications for which the benefit of priority of the subject patent application has been properly claimed, although it is prior to the international filing date.

Document A14 discloses keyhole limpet hemocyanin Type 2 (KLH2): detection and immunolocalization of a labile functional unit *h*. The publication date of Document A14,

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December 30, 1999, is after both of the filing dates of the German patent applications for which the benefit of priority of the subject patent application has been properly claimed, although it is prior to the international filing date.

Document A15 discloses immunoelectron microscopy of hemocyanin from the keyhole limpet (*Megathura Crenulata*): a parallel subunit model.

Document A16 discloses cocaine vaccines: antibody protection against relapse in a rat model.

Document A17 discloses mass determination, subunit organization and control of oligomerization states of keyhole limpet hemocyanin (KLH).

Document A18 discloses suppression of psychoactive effects of cocaine by active immunization.

Document A19 discloses the sequence of a gastropod hemocyanin (HtH1 from *Haliotis Tuberculata*). The publication date of Document A19, February 25, 2000, is after both of the filing dates of the German patent applications for which the benefit of priority of the subject patent application has been properly claimed. This publication discloses work of a co-inventor of the subject application.

Document A20 discloses subunit organization of the abalone haliotis tuberculata hemocyanin type 2 (HtH2). and the cDNA sequence encoding its functional units d, e, f, g and h. The publication date of Document A20, October 1999, is after both of the filing dates of the German patent applications for which the benefit of priority of the subject patent application

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has been properly claimed. This publication discloses work of a co-inventor of the subject application.

Document A21 discloses keyhole limpet hemocyanin: structural and functional characterization of two different subunits and multimers.

Document A22 discloses abalone (*haliotis tuberculata*) hemocyanin type 1 (HtH1) organization of the 400 kDa subunit and amino acid sequence of its functional units f, g and h. The publication date of Document A22, August 1999, is after both of the filing dates of the German patent applications for which the benefit of priority of the subject patent application has been properly claimed. This publication discloses work of a co-inventor of the subject application.

Document A23 discloses a keyhole limpet haemocyanin (KLH): purification of intact KLH1 through selective dissociation of KLH2. This publication discloses work of a co-inventor of the subject application.

Document A24 discloses a quaternary structure, subunits and domain patterns of two discrete forms of keyhole limpet hemocyanin: KLH1 and KLH2. This publication discloses work of a co-inventor of the subject application.

Documents for which the supplied date of publication lists the year of publication without the month were published sufficiently earlier than the effective U.S. filing date and any foreign priority date, so that the particular month of publication is not in issue. Pursuant to §609 of the MPEP, it is understood that the month of publication is not required

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when the particular month of publication is not in issue. Where no date is supplied, it is believed that the date of publication is not in issue.

No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material disclosed is equivalent to the subject invention. In addition, none of the documents that have publication dates prior to the priority date of the above application anticipate the invention in this application.

The cited documents disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the documents and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that the art or document disclosure is otherwise necessarily prior art as defined by the patent law with respect to the instant invention and application.


Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the art and documents recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application. The recitation herein of the art and documents is not to be construed as an assertion that more pertinent art could not possibly be in existence.

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No fee or petition is believed to be necessary. However, should any fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

Respectfully submitted,

By 
Shannon L. Nebolsky, Reg. No. 41,217

Enclosures:

Form PTO-SB08
One Bound Volume of Art A1-A3, A6-A24
Return Mailing Postcard

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120 South Riverside Plaza
Chicago, Illinois 60606
312/655-1500

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Substitute for form 1449A/PTO and 1449B/PTO**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	09/936,852
Filing Date	September 17, 2001
First Named Inventor	Jürgen MARKL, et al.,
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	7911/83687 (GKS 101.0 US)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	5,888,775	3/30/99	Tai, et al.	
	A2	5,831,033	11/3/98	Zetter, et al.	
	A3	5,021,560	6/4/91	Montreuil, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	A6	WO 00/55192	09/21/2000	Biosyn Arzneimittel GMBH		
	A7	WO 94/11019	05/26/94	Zonagen, Inc.		
	A8	EP-0 244 295 A1	11/4/87	Institut Pasteur		X
	A9	EP-0 252 829 A1	01/13/99	Institut Pasteur		X
	A10	EP 0 621 039 A1	10/26/94	Akzo Nobel N.V.		

OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A11	J. V. HAMILTON, et al., "Periodate-Sensitive Immunological Cross-Reactivity Between Keyhole Limpet Haemocyanin (KLH) and Serodiagnostic <i>Schistosoma Mansoni</i> Egg Antigens," <i>Parasitology</i> , 118:83-89 (January 1, 1999).	
	A12	Karen I. MILLER, et al., "Sequence of the <i>Octopus Dofleini</i> Hemocyanin Subunit: Structural and Evolutionary Implications," <i>J. Mol. Biol.</i> 278: 827-842 (May 15, 1998)	
	A13	Stanka STOEVA, et al., "Primary Structure and Unusual Carbohydrate Moiety of Functional Unit 2-c of Keyhole Limpet Hemocyanin (KLH)," <i>Bioclinica et Biophysica Acta.</i> , 1435: 94-109 (November 16, 1999).	
	A14	Wolfgang GEBAUER, et al., "Keyhole Limpet Hemocyanin Type 2 (KLH2): Detection and Immunolocalization of a Labile Functional Unit h, <i>Journal of Structural Biology</i> 128: 280-286 (December 30, 1999)	

Examiner Signature	Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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